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**UNITED STATES DEPARTMENT OF COMMERCE  
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LB-5DEC

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APPLICATION NO. 08/182,183	FILING DATE 06/20/99	LIN L	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO. SYN2257C4-U
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S-225E

U.S. PATENT OPERATIONS/DRC  
M/S 10-1-B-431  
AMGEN INC.  
ONE AMGEN CENTER DRIVE  
THOUSAND OAKS CA 91320-1789

HM22/0615

EXAMINER HAYES, R
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ART UNIT 1645	PAPER NUMBER
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DATE MAILED: 06/15/99

DOCKETED  
3 mo. Final 9-15-99  
Appeal Review 10-15-99  
6 mo Final/NDA 12-15-99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
08/182,183

Applicant(s)  
Lin et al

Examiner  
Robert C. Hayes

Group Art Unit  
1645



☒ Responsive to communication(s) filed on Nov 9, 1998

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 88-92, 94, 117-161, and 165-177 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☒ Claim(s) 88, 118-120, 124, 125, 150-152, 154-157, 165-171, and 175 is/are allowed.

☒ Claim(s) 89, 90, 92, 94, 117, 121-123, 126-135, 138, 140-149, 153, 158-161, and 172-174 is/are rejected.

☒ Claim(s) 91, 136, 137, 139, 176, and 177 is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 42

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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**DETAILED ACTION**

***Response to Amendment***

1. The amendment filed 11/09/98 has been entered.
2. The rejection of claim 88 under 35 U.S.C. 112, first paragraph, for new matter is withdrawn due to the amendment of the claim.
3. The rejection of claims 117, 120, 122-123, 125-151, 153-158, 161-164, 172-174 & 177 under 35 U.S.C. § 112, second paragraph, as being indefinite for the recitation of “ % identity” is withdrawn, due to the amendment or cancellation of these claims.
4. Claims 88, 118-120, 124-125, 150-152, 154-157, 165-171 & 175 are allowed.
5. Claims 91, 137, 139 & 176-177 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
6. Applicant's arguments filed 11/09/98 have been fully considered but they are not deemed to be persuasive.

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7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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8. Claim 136 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 119. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

9. Claims 90, 92, 127-128, 133-135, 138, 140-142, 144 & 159-161 are again rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, for the reasons made of record. Again, it is suggested that amending claim 90, for example, to “an isolated host cell” would more clearly define the invention, in that “transformed or transfected hosts” encompass gene therapy of humans; thereby, necessitating this rejection. As Applicants correctly allege on page 7 of the response, “isolated” is a “commonly used term to ... identify the cells as non-naturally occurring organisms”; versus “transformed or transfected”.

10. Claims 89-90, 92, 94, 117, 121-123, 126-134, 143-149, 158 and amended claims 153 & 172-174 are again rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

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in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record and as follows.

As previously made of record, in contrast to Applicants' assertions on page 8 of the response, "an amino-terminal methionine residue" is contemplated for *only* "bacterial expression systems", versus the broader scope now claimed that encompasses eukaryotic "expression systems"; thereby, constituting new matter.

Similarly to that previous made of record, no proper conception is apparent within the specification for the reduced washing conditions of 2X SSPE and 0.1% SDS at room temperature, which broadens that conceptualized at the time of filing the instant application. In contrast, the proper context on page 63 of the specification is a more stringent final wash at *0.1X* SSPE and 0.1% SDS at *50°C*; thereby, constituting new matter (i.e., as it relates to claims 117, 121, 125 & 153).

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.  
June 9, 1999



ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600